**DOCKET NO.:** FCCC-0004 (99-01; WO/386)

**Application No.:** 09/868,196

Office Action Dated: April 9, 2004

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application. Listing of Claims:

## 1-44. Canceled

- 45. (Currently amended) A method of treating or preventing clinically manifest mammary tumors, comprising the steps of:
  - a) detecting a clinically manifest mammary tumor in a host;
  - b) administering to the a host a first dose of hGC; and
- c) administering to the host one or more subsequent doses of hGC, wherein the first dose and the subsequent doses of hCG are administered in an amount and over a period of time having a clinically manifest mammary tumor an amount of hCG effective to inhibit proliferation of mammary tumor cells, thereby treating the clinically manifest mammary tumors.

## 46-54. Canceled

- 55. (Previously presented) The method of claim 45, wherein the mammary tumor is a primary tumor.
- 56. (Previously presented) The method of claim 55, wherein the mammary tumor is a non-invasive carcinoma.
- 57. (Previously presented) The method of claim 56, wherein the carcinoma is ductal carcinoma in situ or lobular carcinoma in situ.
- 58. (Previously presented) The method of claim 45, wherein the mammary tumor is an invasive carcinoma.
- 59. (Previously presented) The method of claim 58, wherein the carcinoma is tubular or lobular invasive carcinoma.

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60. (Previously presented) The method of claim 45, wherein the mammary tumor is a metastatic mammary tumor.

61. (Previously presented) The method of claim 45, wherein the host is a

premenopausal woman.

62. (Previously presented) The method of claim 45, wherein the host is a

postmenopausal woman.

63. (Currently amended) The method of claim 45, combined with at least one other

treatment for clinically manifest mammary tumors cancer therapy.

64. (Currently amended) The method of claim 63, wherein the at least one other

treatment cancer therapy is surgery or chemotherapy.

65. (Previously presented) The method of claim 45, wherein the mammary tumors

comprise cells that are estrogen receptor-positive.

66-69. Canceled

70. (Previously presented) The method of claim 45, wherein the hCG is administered

in an amount of 100 to 20,000 IU per day.

71. (Previously presented) The method of claim 45, wherein the hCG is administered

in amount of 50 to 50,000 micrograms per day.

72. (Previously presented) The method of claim 71, wherein the hCG is administered

in an amount of 250 to 3,000 micrograms per day.

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73. (Currently amended) The method of claim 45, wherein the <u>one or more</u> subsequent doses of hCG <u>are</u> is administered every second day <u>following administration of</u> the first dose.

74. (Currently amended) The method of claim 45, wherein the <u>one or more</u> subsequent doses of hCG <u>are</u> is administered three times each week <u>following administration</u> of the first dose.

75. (Currently amended) The method of claim 45, wherein the <u>one or more</u> subsequent doses of hCG <u>are</u> is administered for several weeks <u>following administration of</u> the first dose.

76. (Previously presented) The method of claim 75, wherein the hCG is administered for at least 12 weeks.

77. (Previously presented) The method of claim 45, wherein the hCG is administered subcutaneously.

78. (Previously presented) The method of claim 45, wherein the hCG is administered in combination with Type 1 interferon.

79. Canceled.

80. (Previously presented) The method of claim 45, wherein the hCG is recombinant hCG.

81-103. Canceled